

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C. 20231
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

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|--|--|
| Date of mailing (day/month/year) 07 April 2000 (07.04.00) | |
| International application No. PCT/US99/16357 | Applicant's or agent's file reference DEX-0039 |
| International filing date (day/month/year) 20 July 1999 (20.07.99) | Priority date (day/month/year) 04 August 1998 (04.08.98) |
| Applicant SUN, Yongming et al | |

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

29 February 2000 (29.02.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

OCT 20 2000

PCT

To: JANE MASSEY LICATA
LAW OFFICES OF JANE MASSEY LICATA
66 E. MAIN STREET
MARLTON NJ 08053

Docket System ☒
Status Report ☒
Docket Book ☒

NP = 2-4-01

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

17 OCT 2000

Applicant's or agent's file reference

DEX-0039

IMPORTANT NOTIFICATION

International application No.

PCT/US99/16357

International filing date (day/month/year)

20 JULY 1999

Priority Date (day/month/year)

04 AUGUST 1998

Applicant

DIADEXUS LLC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SUSAN UNGAR

Telephone No. (703) 308-0196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

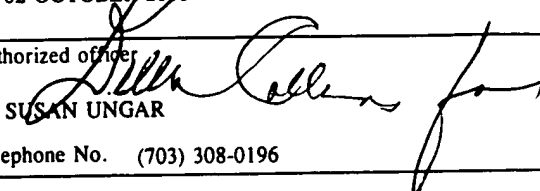
| | | |
|--|--|---|
| Applicant's or agent's file reference DEX-0039 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/US99/16357 | International filing date (day/month/year) 20 JULY 1999 | Priority date (day/month/year) 04 AUGUST 1998 |
| International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet. | | |
| Applicant DIADEXUS LLC | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 29 FEBRUARY 2000 | Date of completion of this report 02 OCTOBER 2000 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer  SUSAN UNGAR |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-0196 |

I. Basis of the report**1. With regard to the elements of the international application:***☒ the international application as originally filed☒ the description:

pages 1-31, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the claims:

pages 32-34, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the drawings:

pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the sequence listing part of the description:

pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
☒ the claims, Nos. NONE
☒ the drawings, sheets/fig. NONE

5. ☒ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☒ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | |
|-------------------------------|-----------------------|-----|
| Novelty (N) | Claims <u>6</u> | YES |
| | Claims <u>1, 2</u> | NO |
| Inventive Step (IS) | Claims <u>6</u> | YES |
| | Claims <u>1,2</u> | NO |
| Industrial Applicability (IA) | Claims <u>1, 2, 6</u> | YES |
| | Claims <u>NONE</u> | NO |

2. citations and explanations (Rule 70.7)

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,733,748.

The claims are drawn to a method for diagnosing the presence of colon cancer, metastatic colon cancer in a patient by measuring the levels of colon specific genes in the cells or tissues of patients and comparing this measurement to normal controls.

US Patent No. 5,733,748 teaches specifically teaches methods of diagnosing colon cancer by measuring the colon specific genes in order to diagnose colon cancer, metastatic colon cancer wherein overexpression is indicative of colon cancer(see col. 2, lines 24-42).

Claim 6 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed method wherein the CSG is SEQ ID NO:1, 2 or 3.

----- NEW CITATIONS -----

NONE

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 51/00, 39/395; C12Q 1/00, 1/68; G01N 33/53; C07K 1/00, 16/00 and US Cl.: 424/1.49, 130.1, 141.1, 178.1; 435/4, 6, 7.1; 530/350, 387.1, 387.9, 388.1, 388.8, 389.7, 391.1, 391.3, 391

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

As applicant was previously notified this International Preliminary Examining Authority has found plural inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1, 2 and 6, drawn to a method for diagnosing the presence of colon cancer in a patient.

Group II, claim(s) 3 and 6, drawn to a method of staging colon cancer in a patient.

Group III, claim(s) 4, 5, 6, drawn to a method of monitoring colon cancer in a patient.

Group IV, claim(s) 7, drawn to an antibody against CSG.

Group V, claim(s) 8-9, drawn to a method of treating colon cancer in a patient.

Group VI, claim(s) 10-11, drawn to a method of treating colon cancer in a patient.

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VI appears to be that they all relate to CSG which is a colon specific gene.

However, US Patent No. 5,733,748 specifically teaches colon specific genes and polypeptides encoded by those genes as well as method of diagnosing colon cancer by measuring the gene products and antibodies specific to the colon specific gene products (see abstract).

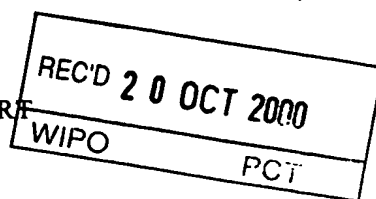
Therefore the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method for diagnosing the presence of colon cancer in a patient.
The special technical feature of Group II is considered to be a method of staging colon cancer in a patient.
The special technical feature of Group III is considered to be a method of monitoring colon cancer in a patient.
The special technical feature of Group IV is considered to be an antibody against CSG.
The special technical feature of Group V is considered to be a method of imaging colon cancer in a patient.
The special technical feature of Group VI is considered to be a method of treating colon cancer.

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

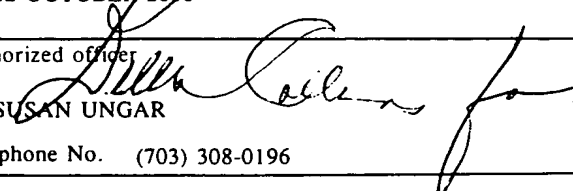


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| Industrial Applicability (IA) | Claims | <u>1, 2, 6</u> | YES |
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I. BASIS OF REPORT:5. (Some) amendments are considered to go beyond the disclosure as filed:
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